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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,146	02/01/2002	Roland Cherif Cheikh	0512-1009-1	1738
<div>466 7590 05/17/2007</div> <div>YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202</div>				
			EXAMINER VU, JAKE MINH	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 05/17/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/060,146

Applicant(s)

CHEIKH, ROLAND CHERIF

Examiner

Jake M. Vu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 75-78 and 80-127 is/are pending in the application.
- 4a) Of the above claim(s) 91-94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 75-78, 80-90 and 95-127 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment filed on 09/19/2006; and Argument filed on 02/20/2007. Claims 74 and 79 have been cancelled. New claims 101-127 have been added. Claims 75-78 and 80-127 are pending in the instant application. Claims 91-94 are withdrawn from consideration.

Election/Restrictions

Applicant's election with traverse of Group I (claims 74-90 and 95-100) in the reply filed on 02/20/2007 is acknowledged. The traversal is on the ground(s) that there is no undue burden on the office to examine all the claims together. This is not found persuasive because searching all of the claims would require searching in numerous different classes and subclasses, as well as a different searching focus depending on whether the product or processes are being searched. Thus, the search would pose an undue burden on the Office.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. While Applicant is entitled to receive benefit of an earlier filing date of 07/21/1999, Applicant has not complied with one or more conditions for receiving the benefit of a filing date of 12/02/1996.

This application is claiming the benefit of prior-filed nonprovisional application No. FR96/14755 under 35 U.S.C. 120, 121, or 365(c). Copendency between the current application and the prior application is required. Since the applications are not copending, the benefit claim to the prior-filed nonprovisional application is improper. Applicant is required to delete the reference to the prior-filed application from the first sentence(s) of the specification, or the application data sheet, depending on where the reference was originally submitted, unless applicant can establish copendency between the applications.

Response to Arguments

Claim 79 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of Applicant's cancellation of claim 79.

Claims 74-77, 80-87, 89, 90, 95-100 rejected under 35 U.S.C. 102(b) as being anticipated by HUTCHINSON (US 5,366,734) **are withdrawn** in view of Applicant's amendment filed on 09/19/2006.

Claims 74-90 and 95-100 rejected under 35 U.S.C. 103(a) as being unpatentable over HUCTHINSON (cited supra) in view of RAMCHANDANI et al (*In vitro and in vivo release of ciprofloxacin from PLGA 50:50 implants*. Journal of Control Release. 1998 Jul 31;54(2):167-75) **are withdrawn** in view of Applicant's amendment filed on 09/19/2006.

However, upon further consideration, a new ground(s) of rejection is made as discussed below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 80, 95, 99, and 100 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 80, 95, 99, and 100 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 80, 95, 99, and 100 recite the newly amended limitation of "above 50% and less than or equal to 80%"; however, the specification as-filed does not provide a written description or set forth the metes and bounds of this phrase. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed and

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now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, introduce new concepts and thus violate the written description requirement of the first paragraph of 35 U.S.C. §112.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to identify sufficient written support in the original specification for the "limitations" indicated above. Applicant indicated that support for this limitation can be found in examples 7 and 9, page 38, lines 10-17 and page 45, lines 23-27. However, examples 7 and 9 only disclose 52%, 70% and 80% of triptoreline; page 38, lines 10-17 only discloses 70-80%; and page 45, lines 23-27 does not disclose any percentages of active ingredients.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 75, 76, 80 and 99 are rejected under 35 U.S.C. 102(b) as being anticipated by AZAIN et al (EP 0283458).

Applicant's claims are directed to a composition comprising of: peptidic active principle, such as somatostatin, wherein the active principle is above 50% and less than or equal to 80%. Wherein the composition is in a rod shape used for implantation.

AZAIN teaches a composition comprising of: peptidic active principle, such as somatostatin, wherein the active principle can exceed 50% (see pg. 7, line 25). Wherein the composition is in a rod shape (see pg. 5, line 56 and line 64) used for implantation (see pg. 2, line 5). Additional disclosure includes polylactide 9 (see pg. 6, line 58).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 75-78, 80-90 and 95-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over DEGHENGHI (WO 98/09613).

As discussed above, AZAIN teaches a composition comprising of: peptidic active principle, such as somatostatin, wherein the active principle can exceed 50% (see pg. 7, line 25). Wherein the composition is in a rod shape (see pg. 5, line 56 and line 64) used for implantation (see pg. 2, line 5). Additional disclosure includes polylactide 9 (see pg. 6, line 58).

DEGHENGHI teaches an implant composition comprised of: LHRH (see pg. 1, line 15) or triptoreline (see claim 10) active agents; copolymer of lactic acid and glycolic acid (see abstract). Wherein the implant is cut into cylindrical rods (see abstract).

The references do not specifically teach some of the specific lengths and diameters and adding the ingredients in the amounts as claimed by Applicant. The amount of a specific ingredient in a composition and shape of the composition are clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal shape and amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

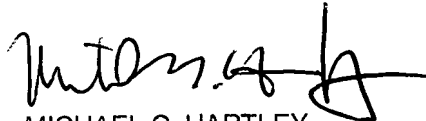
Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571) 272-8148. The examiner can normally be reached on Mon-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jake M. Vu, PharmD, JD
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MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER